

Food And Drug Administration**Open Meeting for Representatives of Health Professional Organizations**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting for representatives of health professional organizations. The meeting will be chaired by Sharon Smith Holston, Deputy Commissioner for External Affairs, FDA. This meeting will provide participants an opportunity to hear a discussion on the prevention of errors in the use of medications and other medical products.

DATES: The meeting will be held on Monday, September 30, 1996, from 1:30 p.m. to 4:30 p.m.

ADDRESSES: The meeting will be held at the Hyatt Regency Hotel, One Bethesda Metro Center, Bethesda, MD. Interested persons may register with Betty Palsgrove at 301-443-1652. Registration also may be transmitted by FAX to 1-800-344-3332 or 301-443-2446.

FOR FURTHER INFORMATION CONTACT: Peter H. Rheinstein, Office of Health Affairs (HFY-40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5470.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to provide an opportunity for representatives of health professional organizations and other interested persons to be briefed by senior FDA staff and to provide an opportunity for informal discussion and comment on the prevention of errors in the use of medications and other medical products.

This public meeting is free of charge; however, space is limited. Registration for the meeting will be accepted in the order received, and should be sent to the contact person listed above. Registration should include the name and title of the person attending and the name of the organization being represented, if any.

Dated: August 23, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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Food and Drug Administration**Investigational Biological Product Trials; Procedure to Monitor Clinical Hold Process; Meeting of Review Committee and Request for Submissions**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a meeting of its clinical hold review committee, which reviews the clinical hold orders that the Center for Biologics Evaluation and Research (CBER) has placed on certain investigational biological product trials. FDA is inviting any interested biological product company to use this confidential mechanism to submit to the committee for its review the name and number of any investigational biological product trial placed on clinical hold during the past 12 months that the company wants the committee to review.

DATES: The meeting will be held in November 1996. Biological product companies may submit review requests for the November meeting by October 1, 1996.

ADDRESSES: Submit clinical hold review requests to Amanda Bryce Norton, FDA Chief Mediator and Ombudsman, Office of the Commissioner (HF-7), Food and Drug Administration, 5600 Fishers Lane, rm. 14-105, Rockville, MD 20857, 301-827-3390.

FOR FURTHER INFORMATION CONTACT: Joy A. Cavagnaro, Center for Biologics Evaluation and Research (HFM-4), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-0379.

SUPPLEMENTARY INFORMATION: FDA regulations in part 312 (21 CFR part 312) provide procedures that govern the use of investigational new drugs and biologics in human subjects. If FDA determines that a proposed or ongoing study may pose significant risks for human subjects or is otherwise seriously deficient, as discussed in the investigational new drug regulations, it may order a clinical hold on the study. The clinical hold is one of FDA's primary mechanisms for protecting subjects who are involved in investigational new drug or biologic trials. Section 312.42 describes the grounds for ordering a clinical hold.

A clinical hold is an order that FDA issues to a sponsor to delay a proposed investigation or to suspend an ongoing investigation. The clinical hold may be ordered on one or more of the

investigations covered by an investigational new drug application (IND). When a proposed study is placed on clinical hold, subjects may not be given the investigational drug or biologic as part of that study. When an ongoing study is placed on clinical hold, no new subjects may be recruited to the study and placed on the investigational drug or biologic, and patients already in the study should stop receiving therapy involving the investigational drug or biologic unless FDA specifically permits it.

When FDA concludes that there is a deficiency in a proposed or ongoing clinical trial that may be grounds for ordering a clinical hold, ordinarily FDA will attempt to resolve the matter through informal discussions with the sponsor. If that attempt is unsuccessful, a clinical hold may be ordered by or on behalf of the director of the division that is responsible for the review of the IND.

FDA regulations in § 312.48 provide dispute resolution mechanisms through which sponsors may request reconsideration of clinical hold orders. The regulations encourage the sponsor to attempt to resolve disputes directly with the review staff responsible for the review of the IND. If necessary, the sponsor may request a meeting with the review staff and management to discuss the clinical hold.

CBER began a process to evaluate the consistency and fairness of practices in ordering clinical holds by instituting a review committee to review clinical holds (see 61 FR 1033, January 11, 1996). CBER held its first clinical hold review committee meeting on May 17, 1995, and plans to conduct further quality assurance oversight of the IND process. The committee last met in May 1996. The review procedure of the committee is designed to afford an opportunity for a sponsor who does not wish to seek formal reconsideration of a pending clinical hold to have that clinical hold considered "anonymously." The committee consists of senior managers of CBER, a senior official from the Center for Drug Evaluation and Research, and the FDA Chief Mediator and Ombudsman.

Clinical holds to be reviewed will be chosen randomly. In addition, the committee will review some of the clinical holds proposed for review by biological product sponsors. In general, a biological product sponsor should consider requesting review when it disagrees with FDA's scientific or procedural basis for the decision.

Requests for committee review of a clinical hold should be submitted to the FDA Chief Mediator and Ombudsman, who is responsible for selecting clinical